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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/734,063
Filing Date: December 10, 2003
Appellant(s): MARLOWE ET AL.

Peter G. Thurlow
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 8/7/2007 appealing from the Office action mailed 11/30/2006.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4780423

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bluestein et al. (US P/N 4,780,423) in view of Lucas (US P/N 6,996,538).

The claimed invention is directed to a method for preparing a binding-ready biological sample to be used in a said binding assay and an automated inventory checking system. The method involves receiving a design for a binding assay, preparing an experiment design and choosing a robot method for generating said binding-ready biological sample, generating work instructions, and executing said work instructions on robot stations to generate the binding-ready biological sample. The method also involves an automation method for checking supplies and materials required for experiment design and ascertaining whether there are enough materials in inventory.

Bluestein teaches the limitations of as recited in claim 14 at col. 6, lines 35-48, col. 8, lines 10-67, and col. 9, lines 1-30. Bluestein at col. 9, lines 13-19 teaches the automated method step of adding 30 ul of the CPG reagent to each well of the microtiter plate, wherein the biological sample, the CPG reagent, being automatically aliquoted and deposited prior to performing other assay steps is interpreted as being a step of a computer implemented method for preparing a binding-ready biological sample for a binding assay as recited in the **preamble**. Bluestein et al. teaches the **first step** of

claim 14 at col. 6, lines 35-48. Bluestein et al. discusses receiving an IMMOPHASE radioimmunoassay kit for performing an assay as required in the first step, which recites receiving a binding assay design. Bluestein et al. teaches the **second step** of claim 14 at col. 8, lines 10-31. Bluestein et al. explicitly discusses changes made in the radioimmunoassay kit used in Example 1 as preparative steps for designing an experiment for generating a binding-ready biological sample, which reads on preparing an experiment design for generating a binding-ready biological sample. Bluestein et al. teaches the **third step** of claim 14 at col. 8, lines 61-69 and col. 9, lines 1-30. Bluestein et al. discusses the use of the Screen Machine System manufactured by Pandex Laboratories as the choice of a robot method for generating a binding ready biological sample and executing work instructions on robot stations to generate the binding ready biological sample. At col. 9, lines 8-13, Bluestein et al. discusses a microprocessor that can be programmed for generating work instructions for generating biological samples, such as adding wash solutions and reagents. At col. 9, lines 13-15, Bluestein et al. discusses the execution of work instructions for generating the biological sample using the SCREEN MACHINE.

Bluestein et al. teaches claim 15 at col. 8. Bluestein et al. teaches optimizing materials usage and plate layout for generating a biological sample at Col. 8, lines 15-26 and lines 53-57, where changes were made for creating high precision capabilities and a comparison shows that the assay of this invention is capable of achieving more rapid test results, which is a result of optimizing materials usage and plate layout.

Bluestein et al. teaches some of the limitations of claims 20 and 22 at col. 4, lines 62-69 and col. 5, lines 1-4. Bluestein discusses the biological sample as being a receptor tissue protein. Bluestein also discusses the assay as comprising a ligand and a specific binding partner to the ligand, which is a type of hybridization assay.

Bluestein et al. teaches part of claim 21 at col. 4, lines 62-69 and col. 5, lines 1-4. Bluestein discusses the biological sample as being a receptor tissue protein. The sample in the assay is a receptor tissue protein, which indicates that the constituent sample was acquired and extracted at some point. However, Bluestein does not explicitly teach extracting a constituent sample from said tissue sample and updating inventory after extracting a constituent sample.

Additionally, Bluestein et al. does not teach an automation method for checking supplies and ascertaining whether there are enough materials in inventory, sending a request, and notifying an operator if there are not enough materials in inventory.

Lucas teaches at col. 2 and col. 3, lines 3-17 an automated inventory management system where constituent samples/items are obtained from samples/supplies and the inventory management system is updated after extracting/sending the constituent sample/item.

Lucas further teaches checking inventory for required materials, as recited in claim 16, at col. 2, Lines 45-53. Lucas discusses an inventory management system, which automatically checks supplies and materials required as needed.

Lucas discusses sending an inventory request, receiving a list of materials and ascertaining whether there are enough materials, as recited in claim 17, at col. 8, lines 65-67 and col. 9, lines 1-10.

Lucas discusses sending an inventory request containing a list of materials as a customer selecting search criteria which queries a list of products and product descriptions that match the inventory request and returns the information, as recited in claim 18, at col. 9, lines 63-67 and col. 10, lines 1-53.

Lucas discusses sending inventory requests when not enough materials may be available and notifying an operator or sales consultant and continue scanning orders until requests are fulfilled, as recited in claim 19, at col. 10, lines 33-68 and col. 11, lines 1-46.

Lucas teaches part of claim 20 at col. 9, lines 50-55, wherein Lucas discusses updating customer inventory.

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Bluestein et al. with Lucas wherein the motivation would have been to enhance the automation of the automation system of generating a binding assay using the automating inventory checking system of Lucas.

(10) Response to Argument

Appellant alleges that nothing in Bluestein would disclose or suggest to a person of ordinary skill in the art a computer implemented method for ***preparing a binding-ready biological sample*** for a binding assay. Appellant further alleges that the Bluestein reference only describes an automated method for the immunoassay.

Appellant 's allegations are not found persuasive as it is the CPG reagent of Bluestein, which is considered to be the "binding-ready biological sample." Bluestein teaches steps of receiving a binding assay design (i.e. receiving an IMMOPHASE radioimmunoassay kit), preparing an experiment design (i.e. changes made in the radioimmunoassay kit used in Example 1 as preparative steps for designing an experiment in which the CPG will be used), choosing a robot method (the Screen Machine System), and generating and executing work instructions for "generating" the binding ready sample (i.e. an automated method step of adding 30 ul of the CPG reagent to each well of the microtiter plate, wherein the CPG reagent is automatically aliquoted and deposited prior to performing other assay steps), as set forth in the rejection above. Furthermore, Appellant 's arguments are not commensurate in scope with the limitations actually recited in the claims as the claims, do not, in fact, recite any method step of ***preparing*** *a binding-ready biological sample.* While the entirety of claim 14, for example, appears to result in such "preparation," no actual method step of "preparing" a sample is recited. As Bluestein teaches all of the method steps actually recited in the claims, the examiner maintains that Bluestein does, in fact, teach a method of preparing a binding-ready biological sample.

It is noted that appellants admit, on page 5 of the Brief, that Bluestein, in particular columns and lines, such as at column 7, lines 20-25, discloses samples that are binding-ready and already prepared, but further allege that "there is no description of preparing the sample as recited in claim 14."

Appellant further alleges that nothing in Bluestein would disclose "preparing an experiment design for generating a binding-ready biological sample."

Appellant 's allegations are not found persuasive as Bluestein et al. teaches this step at col. 6, lines 25-60 and col. 8, lines 10-31. Bluestein et al. at col. 8 explicitly discusses changes made in the radioimmunoassay kit used in Example 1 as preparative steps for designing an experiment for generating a binding-ready biological sample, which reads on "preparing an experiment design for generating a binding-ready biological sample."

Appellant submits that the Pandex Screen Machine described in these sections automatically performs the immunoassay, but further alleges that nothing in these sections would disclose "preparing a binding-ready biological sample."

Appellant 's allegations are not found persuasive as Appellant 's arguments are not commensurate in scope with the limitations of the claim as the limitations do not recite method steps for "preparing *a binding-ready biological sample.*"

Appellant submits that at col. 9, lines 8-12, Bluestein discloses that the Pandex Screen Machine can be programmed to add reagents and wash solutions for immunoassays. However, Appellant alleges that adding the reagents and wash solutions as recited is adding, not **preparing** substances used in the immunoassay.

Appellant 's allegations are not found persuasive as Appellant 's arguments are not commensurate in scope with the limitations of the claim as the limitations do not recite method steps for "*preparing substances used in the immunoassay.*" Moreover, Appellant s allegations are not found persuasive because Bluestein at col. 9, lines 13-19

teaches the automated method step of adding 30 ul of the CPG reagent (i.e. a binding-ready biological sample) to each well of the microtiter plate, wherein the the steps of automatically aliquoting and depositing the CPG reagent prior to performing other assay steps is interpreted as being a step of "executing...work instructions on robot stations..." and the totality of the steps taught by Bluestein are interpreted to be a computer implemented method for preparing a binding-ready biological sample, which is used in the immunoassay.

Appellant further alleges that "nowhere in Bluestein is there any hint or suggestion of using the SCREEN MACHINE system, or any other method, to **generate the binding ready biological samples to be used in the immunoassay."**

Appellant 's allegations are not found persuasive as the claims do not actually recite method steps of "*generating the binding ready biological samples to be used in the immunoassay."* Further, the Bluestein does teach steps of executing work instructions on an automated machine (robot stations) to prepare or "generate" the CPG reagent in a format for further use in a binding assay. Thus, the examiner maintains that Bluestein does teach a step of executing work instructions...to generate the binding-ready biological sample, as set forth above.

Appellant discusses the MacCrindle reference and discusses how the samples in the MacCrindle reference are prepared and binding ready prior to processing by the Screen Machine wherein the Screen Machine only performs the immunoassay. Appellant then alleges that examples 1, 2, and 3 do not have "automated preparations of binding-ready biological samples."

Appellant 's allegations are not found persuasive as Appellant 's arguments again are not commensurate in scope with the limitations of the claim as the claims do not, in fact, recite method steps for the "*automated preparations of binding-ready biological samples.*" As Bluestein does teach steps of executing work instructions on an automated machine (robot stations) to prepare or "generate" the CPG reagent in a format for further use in a binding assay, the examiner maintains that Bluestein does teach a step of executing work instructions on robot stations to generate the binding-ready biological sample, as set forth above.

Appellant further alleges that adding controlled pore glass (CPG) antibody and fluorescein labeled anti-ferritin antibody are steps in an immunoassay, i.e. adding the reagents to the binding-ready biological sample (ferritin), and does not represent "a robot method for generating said binding-ready biological sample." In response, it is noted that the CPG reagent of Bluestein is interpreted to be a "binding-ready biological sample," not ferritin. For the reasons set forth above, the examiner maintains that Bluestein does, in fact, teach steps of preparing/generating this reagent preparatory for use in a binding assay. Specifically with regard to a "robot method," Bluestein et al. [[teaches this step of claim 14 at col. 8, lines 61-69 and col. 9, lines 1-30. Bluestein et al.]] discusses the use of the Screen Machine System manufactured by Pandex Laboratories as the choice of a robot method for generating a binding ready biological sample and executing work instructions on robot stations to generate the binding ready biological sample. At col. 9, lines 8-12, Bluestein et al. discusses a microprocessor that

can be programmed for generating work instructions for generating biological sample, such as adding wash solutions and reagents. At col. 9, lines 13-15, Bluestein et al. discusses the execution of work instructions for generating the biological sample using the SCREEN MACHINE. Bluestein at col. 9, lines 13-19 teaches the automated method step of adding 30 ul of the CPG reagent to each well of the microtiter plate, wherein the biological sample, the CPG reagent, is automatically aliquoted and deposited prior to performing other assay steps, and is therefore interpreted as choosing a robot method for generating a binding-ready biological sample.

Appellant further argues that the automated performance of the immunoassay such as depositing the CPG antibody to each tube does not deal with "preparing a binding-ready biological sample as required by claim 14." Appellant s further allege that the addition of binding reagents to a binding-ready biological sample is not the preparation of a binding-ready biological sample.

Appellant 's arguments are not found persuasive as Appellant 's arguments are not commensurate in scope with the limitations of the claim as the limitations do not recite method steps for "***preparing*** *a binding-ready biological sample.*"

Appellant further alleges that Lucas would not remedy any of the deficiencies discussed above in regard to Bluestein since it is directed to an inventory control system and would not teach a person of ordinary skill in the art a computer implemented method for preparing a binding-ready biological sample for a binding assay that includes the steps recited in claim 14.

Again, Appellant 's arguments are not found persuasive as Appellant 's arguments are not commensurate in scope with the limitations of the claim as the limitations do not recite method steps for "*preparing a binding-ready biological sample.*" Moreover, the Lucas reference was not used to remedy any of the deficiencies discussed above in regard to Bluestein as the above discussion **only** pertained to claim 14 wherein the examiner maintains that Bluestein does teach a computer implemented method for preparing a binding-ready biological sample for a binding assay that includes the steps recited in claim 14 as discussed above.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Jason Sims/

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11/26/2007

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